UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

UNITED STATES OF AMERICA,

Plaintiff,

Case No. 15-C-927

v

ATRIUM, INC., ASPEN GROUP, INC., and NUTRI-PAK OF WISCONSIN, INC., corporations, and JAMES F. SOMMERS, and ROBERTA A. SOMMERS, individuals,

Defendants.

CONSENT DECREE OF PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned attorneys, having filed a Complaint For Permanent Injunction ("Complaint") against Atrium, Inc., Aspen Group, Inc., and Nutri-Pak of Wisconsin, Inc., corporations, and James F. Sommers and Roberta A. Sommers, individuals (collectively, "Defendants"), and Defendants having appeared and having consented to the entry of this Consent Decree of Permanent Injunction ("Decree") without contest, without admitting or denying the allegations of the Complaint, and before any testimony has been taken, and the United States of America having consented to this Decree;

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED that:

1. This Court has jurisdiction over the subject matter of this action and has personal jurisdiction over all parties to this action pursuant to 28 U.S.C. §§ 1331, 1337, and 1345, and 21 U.S.C. § 332. Venue is proper in this district under 28 U.S.C. §§ 1391(b) and (c).

2. The complaint states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-399f (the "Act").

3. The complaint alleges that Defendants violate the Act, 21 U.S.C. § 331(a), by introducing or causing to be introduced, and delivering or causing to be delivered for introduction, into interstate commerce articles of food (dietary supplements as defined by 21 U.S.C. § 321(ff)) that are adulterated, within the meaning of 21 U.S.C. § 342(g)(1), in that they have been prepared, packed, and held under conditions that do not conform to the current good manufacturing practice ("cGMP") regulations for dietary supplements set forth at 21 C.F.R. Part 111, and misbranded within the meaning of 21 U.S.C. § 343.

4. Upon entry of this Decree, Defendants represent to the Court that Defendants are not directly or indirectly engaged in the manufacturing, preparing, packing, repackaging, labeling, holding, and/or distributing of any dietary supplements. If Defendants later intend to resume any such activities, Defendants must first notify the United States Food and Drug Administration ("FDA") in writing at least sixty (60) business days in advance of resuming operations and comply with paragraphs 5(A)-(C) of this Decree. Defendants shall not resume such activities until FDA has inspected Defendants' facility and operations at 460 S Townline Road, Wautoma, Wisconsin 54982, or at or from any other locations at which Defendants now, or in the future, directly or indirectly manufacture, prepare, pack, repack, label, hold, and/or distribute dietary supplements ("the facility"), as and when FDA deems necessary, pursuant to paragraph 5(D), Defendants have paid all costs pursuant to paragraph 5(E), and Defendants have received written notice from FDA,

as required by paragraph 5(F). Then Defendants shall resume operations only to the extent authorized in FDA's written notice.

5. Upon entry of this Decree, Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons or entities in active concert or participation with any of them (including individuals, partnerships, corporations, subsidiaries, franchisees, affiliates, and "doing business as" entities), who receive actual notice of this Decree, are hereby permanently restrained and enjoined, under the provisions of 21 U.S.C. § 332(a), and the equitable authority of this Court, from directly or indirectly manufacturing, preparing, packing, repackaging, labeling, holding, and/or distributing any dietary supplements, at or from any locations at which Defendants, in the future, directly or indirectly manufacture, prepare, pack, repack, label, hold, and/or distribute dietary supplements unless and until:

A. Defendants' facility, methods, processes, and controls used to manufacture, prepare, pack, repack, label, hold, and distribute dietary supplements are established, operated, and administered in compliance with this Decree, the Act, and its implementing regulations;

B. Defendants retain, at their expense, an independent person or persons (the "cGMP Expert"), who is without any personal or financial ties (other than the retention agreement) to Defendants or their families, and who, by reason of background, training, education, or experience, is qualified to inspect the facility to determine whether Defendants' facility, methods, processes, and controls are operated and administered in conformity with cGMP, 21 C.F.R. Part 111, and:

i. Defendants shall notify FDA in writing of the identity and qualifications of the cGMP Expert within five (5) business days of retaining such Expert;

ii. The cGMP Expert performs a comprehensive inspection of the facility and the methods, processes, and controls that Defendants use to manufacture, prepare, pack, repack, label, hold, and distribute dietary supplements to determine whether Defendants are in compliance with this Decree, 21 U.S.C. § 342(g)(1), and 21 C.F.R. Part 111;

iii. Defendants report to FDA in writing actions they have taken to:

a. Correct all deviations brought to Defendants' attention by FDA, the cGMP Expert, and/or any other source; and

b. Ensure that the methods and processes used in, and the facility and controls used for, manufacturing, preparing, packing, repackaging, labeling, holding, and distributing dietary supplements are operated, and will be continuously administered in conformity with cGMP, 21 C.F.R. Part 111; and

iv. The cGMP Expert certifies in writing to FDA that:

a. The cGMP Expert has inspected the facility and the methods, processes, and controls that Defendants use to manufacture, prepare, pack, repack, label, hold, and distribute dietary supplements;

b. All cGMP deviations brought to Defendants' attention by FDA, the cGMP Expert, or any other source have been corrected; and

c. The facility, methods, processes, and controls that Defendants use to manufacture, prepare, pack, repack, label, hold, and distribute dietary supplements are in compliance with this Decree, the Act, and 21 C.F.R. Part 111. As part of the cGMP Expert's

certification, a full, complete, and detailed report of the results of the cGMP Expert's inspection(s), including documentation of the corrections of cGMP deviations, shall be provided to FDA;

C. Defendants retain, at their expense, an independent person or persons (the "Labeling Expert"), who is without any personal or financial ties (other than the retention agreement) to Defendants or their families, except that the Labeling Expert may be the same person(s) as the cGMP Expert, and who, by reason of background, training, education, or experience, is qualified to determine whether Defendants' products are labeled in compliance with the Act and its implementing regulations, including, but not limited to, the food labeling requirements, see, e.g., 21 C.F.R. Part 101, and:

i. Defendants shall notify FDA in writing of the identity and qualifications of the Labeling Expert within five (5) business days of retaining such Labeling Expert;

ii. The Labeling Expert performs a review of each and all of Defendants' products' labels and labeling to determine whether each product's labels and labeling comply with the Act and its implementing regulations, including, but not limited to, the food labeling requirements;

iii. Within twenty (20) business days after the review described in paragraph 5(C)(ii) is completed, the Labeling Expert prepares and submits contemporaneously to FDA and Defendants, by courier service or overnight delivery service, a written report of the review, which shall include a list of observed deviations, if any, from compliance with the Act and its implementing regulations;

iv. Defendants notify FDA and the Labeling Expert in writing of the actions they have taken to correct all deviations listed in the Labeling Expert's report, if any;

v. The Labeling Expert certifies to FDA in writing that all of Defendants' products' labels and labeling comply with the Act, and its implementing regulations and provides copies of all labels and labeling;

D. FDA, as and when it deems necessary to evaluate Defendants' compliance with the terms of this Decree, the Act, and its implementing regulations, conducts inspections of the facility, including the buildings, equipment, utensils, dietary supplements, labeling, and all relevant records contained therein;

E. Defendants have paid all costs of FDA's supervision, inspections, investigations, analyses, examinations, and reviews with respect to paragraph 5, at the rates set forth in paragraph 11 below; and

F. FDA has notified Defendants, in writing, that Defendants appear to be in compliance with all the requirements specified in subparagraphs 5(A)–(C) and (E) of this Decree, the Act, including 21 U.S.C. §§ 342(g)(1) and 343, and all applicable regulations, including 21 C.F.R. Parts 101 and 111. In no circumstance shall FDA's silence be construed as a substitute for written notification.

6. Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons or entities in active concert or participation with any of them (including individuals, partnerships, corporations, subsidiaries, franchisees, affiliates, and "doing business as" entities), who have received actual notice of this Decree, are permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly doing or causing an act that:

A. violates the Act, 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, or causing the introduction or delivery for introduction into interstate commerce, articles of food (dietary supplements within the meaning of 21 U.S.C. § 321(ff)), that are adulterated within the meaning of 21 U.S.C. § 342(g)(1) or misbranded within the meaning of 21 U.S.C. § 343; and

B. results in the failure to implement and continuously maintain the requirements of this Decree, the Act, and its implementing regulations.

7. Within fifteen (15) business days of entry of this Decree, Defendants shall, pursuant to a method approved in advance in writing by FDA, and under FDA supervision as and when FDA deems necessary, destroy all dietary supplements in Defendants' possession, custody, and/or control. Defendants shall reimburse FDA for supervising the destruction at the rates set forth in paragraph 11 of this Decree. Defendants shall not dispose of any dietary supplements in a manner contrary to any federal, state, or local laws.

8. If Defendants resume activities pursuant to paragraph 4, then after Defendants have complied with paragraphs 5(A)–(C) and (E), and FDA has notified them pursuant to paragraph 5(F), and Defendants have resumed manufacturing, preparing, packing, repacking, labeling, holding, and/or distributing dietary supplements, Defendants shall retain an independent person or persons who shall meet the criteria described in paragraphs 5(B) and (C), and who may be the same person or persons retained as the cGMP Expert and/or Labeling Expert pursuant to paragraph 5(B) and (C), to conduct audit inspections of their dietary supplement manufacturing and labeling

operations (hereinafter, the "Auditor") at least once every six (6) months, for a period of no less than five (5) years.

A. At the conclusion of each audit inspection, the Auditor shall prepare a detailed written report ("audit report") analyzing whether Defendants are in compliance with this Decree, the Act, and its implementing regulations and identifying any deviations ("audit report observations"). As part of every audit report, except the first audit report, the Auditor shall assess the adequacy of corrective actions taken by Defendants to correct all previous audit report observations. The audit reports shall be delivered contemporaneously to Defendants and FDA, by courier service or overnight delivery service, no later than ten (10) business days after the date the audit inspection(s) is completed. In addition, Defendants shall maintain the audit reports in separate files at their facility and shall promptly make the audit reports available to FDA upon request.

B. If an audit report contains any observations indicating that Defendants are not in compliance with this Decree, the Act, and/or its implementing regulations, Defendants shall, within fifteen (15) business days after receiving the audit report, correct those observations, unless FDA notifies Defendants that a shorter time period is necessary. If, after receiving the audit report, Defendants believe that a correction of the deviations will take longer than fifteen (15) business days, Defendants shall, within five (5) business days after receiving the audit report, submit to FDA in writing a proposed schedule for completing corrections ("correction schedule"). The correction schedule must be reviewed and approved by FDA in writing prior to implementation by Defendants. In no circumstance shall FDA's silence be construed as a substitute for written approval. Defendants shall complete all corrections according to the approved correction schedule. Within thirty (30) business days after Defendants receive an audit report, unless FDA notifies Defendants that a shorter time period is necessary, or within the time frame provided in a correction

schedule approved by FDA, the Auditor shall review the actions taken by Defendants to correct the audit report observations. Within five (5) business days after beginning that review, the Auditor shall report in writing to FDA whether each of the audit report observations has been corrected and, if not, which audit report observations remain uncorrected.

9. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of Defendants' operations, and without prior notice, to take any other measures necessary to monitor and ensure continuous compliance with the terms of this Decree, the Act, and all applicable regulations. During such inspections, FDA representatives shall be permitted: immediate access to Defendants' facilities including, but not limited to, all buildings, equipment, finished and unfinished materials and products, containers, labeling, packaging material, and other material therein; to take photographs and make video recordings; to take samples of Defendants' finished and unfinished materials and products, containers, labeling, packaging material, and other material; and to examine and copy all records relating to the manufacturing, preparing, packing, repacking, labeling, holding, and distributing of any and all of Defendants' products. The inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is separate from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

10. Defendants shall promptly provide any information or records to FDA upon request regarding the manufacturing, preparing, packing, repacking, labeling, holding, and distributing of articles of food (dietary supplements).

11. Defendants shall reimburse FDA for the costs of all FDA inspections, investigations, supervision, analyses, examinations, sampling, testing, reviews, document preparation, travel, and subsistence expenses that FDA deems necessary to evaluate Defendants' compliance with any part of this Decree. The costs of such activities shall be borne by Defendants at the prevailing rates in effect at the time the costs are incurred, and Defendants shall make payment in full to FDA within thirty (30) business days of receiving written notification from FDA of the costs. As of the date this Decree is signed by the parties, these rates are: $89.35 per hour and fraction thereof per representative for inspection or investigative work; $107.09 per hour and fraction thereof per representative for analytical or review work; $0.575 per mile for travel expenses by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per-day, per-representative for subsistence expenses, where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified by the General Services Administration or statute, these rates shall be increased or decreased without further Order of the Court.

12. Within ten (10) business days after entry of this Decree, Defendants shall post a copy of this Decree in a conspicuous location in a common area at the facility (including any other location(s) at which Defendants manufacture, prepare, pack, repack, label, hold, and/or distribute dietary supplements), and shall ensure that the Decree remains posted at each location for as long as Defendants' operations at the facility at that location are open. Within fifteen (15) business days after entry of this Decree, Defendants shall provide to FDA an affidavit, from a person with

personal knowledge of the facts stated therein, stating the fact and manner of Defendants' compliance with this paragraph.

13. Within ten (10) business days after entry of this Decree, Defendants shall hold a general meeting or series of smaller meetings for all employees, at which they shall describe the terms and obligations of this Decree. Within fifteen (15) business days after entry of this Decree, Defendants shall provide to FDA an affidavit, from a person with personal knowledge of the facts stated therein, stating the fact and manner of Defendants' compliance with this paragraph, and a copy of the agenda, list of attendees, and meeting minutes from the meeting(s) held pursuant to this paragraph.

14. Within ten (10) business days after entry of this Decree, Defendants shall provide a copy of the Decree, by personal service or certified mail (restricted delivery, return receipt requested), to each and all of Defendants' current directors, officers, agents, representatives, employees, attorneys, successors, assigns, parties for whom Defendants contractually manufacture dietary supplements, and any and all persons or entities in active concert or participation with any of them (including individuals, partnerships, corporations, subsidiaries, franchisees, affiliates, and "doing business as" entities) (collectively referred to as "Associated Persons"). Within fifteen (15) business days after entry of this Decree, Defendants shall provide to FDA an affidavit, from a person with personal knowledge of the facts stated therein, stating the fact and manner of Defendants' compliance with this paragraph, and identifying the names, addresses, and positions of all persons who received a copy of this Decree pursuant to this paragraph, and attaching a copy of the executed certified mail return receipts.

15. In the event that any Defendant becomes associated with any additional Associated Person(s) regarding the manufacturing, preparing, packing, repacking, labeling, holding, and/or distributing of dietary supplements at any time after entry of this Decree, Defendants immediately shall provide a copy of this Decree, by personal service or certified mail (restricted delivery, return receipt requested) to such Associated Person(s). Within ten (10) business days of each time that any Defendant becomes associated with any additional Associated Person, Defendants shall provide to FDA an affidavit, from a person with personal knowledge of the facts stated therein, stating the fact and manner of Defendants' compliance with this paragraph, and identifying the names, addresses, and positions of all Associated Persons who received a copy of this Decree pursuant to this paragraph, and attaching a copy of the executed certified mail return receipts. Within ten (10) business days of receiving a request from FDA for any information or documentation that FDA deems necessary to evaluate Defendants' compliance with this paragraph, Defendants shall provide such information or documentation to FDA.

16. Defendants shall notify FDA, in writing, at least ten (10) business days before any change in ownership, character, or name of their business, including reorganization, relocation, dissolution, bankruptcy, assignment, sale resulting in the emergence of a successor business or corporation, the creation or dissolution of subsidiaries, or any other change in the corporate structure or identity of Atrium, Inc., Aspen Group, Inc., or Nutri-Pak of Wisconsin, Inc., or any of their parents or subsidiaries, or the sale or assignment of any business assets, such as buildings, equipment, or inventory, that may affect obligations arising out of this Decree. Defendants shall provide a copy of this Decree to any prospective successor or assign at least ten (10) business days prior to any sale or assignment. No later than ten (10) business days prior to such assignment or

change in ownership, Defendants shall provide to FDA an affidavit, from a person with personal knowledge of the facts stated therein, stating the fact and manner of Defendants' compliance with this paragraph.

17. If, at any time after entry of this Decree, FDA determines, based on the results of an inspection, the analysis of a sample, a report or data prepared or submitted by Defendants, the cGMP or Labeling Expert, the Auditor, or any other information, that Defendants have failed to comply with any provision of this Decree, have violated the Act or its implementing regulations, or that additional corrective actions are necessary to achieve compliance with this Decree, the Act, and/or its implementing regulations, FDA may, as and when it deems necessary, order Defendants in writing to take appropriate action, including, but not limited to, ordering Defendants immediately to take one or more of the following actions:

A. Cease manufacturing, preparing, packing, repackaging, labeling, holding and/or distributing any or all dietary supplement(s);

B. Recall, at Defendants' own expense, any dietary supplement that, in FDA's judgment, is adulterated, misbranded, or otherwise in violation of this Decree, the Act, and/or its implementing regulations;

C. Revise, modify, or expand any reports, plans, procedures, and/or other records prepared pursuant to this Decree;

D. Submit additional notifications, reports, or any other materials or information to FDA;

E. Institute or re-implement any of the requirements set forth in this Decree;

F. Issue a public notification, public health advisory, and/or press release; and/or

G. Take any other corrective actions as FDA, in its discretion, deems necessary to protect the public health and/or to bring Defendants into compliance with this Decree, the Act, and/or its implementing regulations. Defendants shall pay all cost of recalls and other corrective actions, including the costs of FDA's inspections, investigations, supervision, analyses, examinations, sampling, testing, reviews, document preparation, travel, and subsistence expenses to implement and monitor recalls and other corrective actions, at the rates specified in paragraph 11. This provision shall be separate and apart from, and in addition to, all other remedies available to FDA.

18. Upon receipt of any order issued by FDA pursuant to paragraph 17, Defendants shall immediately and fully comply with the terms of the order. Any cessation of operations or other actions described in paragraph 17 shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with this Decree, the Act, and its implementing regulations, and that Defendants may resume operations.

19. If any Defendant fails to comply with any of the provisions of this Decree, the Act, and/or its implementing regulations, then Defendants shall pay to the United States of America the sum of ten thousand dollars ($10,000) in liquidated damages for each day such violation continues and an additional sum of ten thousand dollars ($10,000) in liquidated damages for each violation of this Decree, the Act, and/or implementing regulations, and an additional sum in liquidated damages equal to twice the retail value of each shipment of dietary supplements that are adulterated

or otherwise in violation of this Decree, the Act, or its implementing regulations. Defendants understand and agree that the liquidated damages specified in this paragraph are not punitive in nature and their imposition does not in any way limit the ability of the United States of America to seek, or the Court to impose, additional civil or criminal penalties to be paid by Defendants, or remedies based on conduct that may also be the basis for payment of liquidated damages pursuant to this paragraph.

20. Should the United States of America bring, and prevail in, a contempt action to enforce the terms of this Decree, Defendants shall, in addition to other remedies, reimburse the United States of America for its attorneys' fees (including overhead), travel expenses incurred by attorneys and witnesses, expert witness fees, administrative and court costs, investigation and analytical expenses incurred in bringing the contempt action, and any other costs or fees related to the contempt proceedings.

21. All decisions specified in this Decree shall be vested in the discretion of the FDA. FDA's decisions shall be final and, to the extent these decisions are subject to review, shall be reviewed by the Court under the arbitrary and capricious standard set forth in 5 U.S.C. §706(2)(A). Review by the Court of any FDA decision rendered pursuant to this Decree shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

22. All notifications, correspondence, and communications to FDA required by the terms of this Decree shall be prominently marked "Decree Correspondence," shall reference this

civil action by case name and civil action number, and shall be addressed to Director, FDA Minneapolis District Office, 250 Marquette Ave Suite 600, Minneapolis, MN 55401, or to the Director at any future address of the FDA Minneapolis District Office. All notifications, correspondence, and communications to Defendants regarding this Decree shall be prominently marked "Decree Correspondence," shall reference this civil action by case name and civil action number, and shall be addressed to Defendants and also to Olson Legal Group LLC, Attorney Nathan P. Olson, 146 Algoma Blvd. Suite A, Oshkosh, WI 54901. FDA shall send notifications, correspondence, and communications regarding this Decree to Defendants and also to a future address or different person if designated in a written communication signed by Mr. Olson or the Defendants and sent to FDA as directed above.

23. This Court retains jurisdiction over this action and the parties thereto for the purpose of enforcing and modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

SO ORDERED this 4th day of August, 2015.

s/ William C. Griesbach
William C. Griesbach, Chief Judge
United States District Court

We hereby consent to the entry of this Decree:

For Defendants:

JAMES F. SOMMERS, individually
and on behalf of Atrium, Inc.,
Aspen Group, Inc., and
Nutri-Pak of Wisconsin, Inc.

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